Translation

PCT/JP2003/003804

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference PCT2046HM | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| International application No. PCT/JP2003/003804 | International filing date (*day/month/year*) 27 March 2003 (27.03.2003) | Priority date (*day/month/year*) |
| International Patent Classification (IPC) or national classification and IPC A61K 9/20, 9/48, 45/00, 47/30, 31/513, 31/58, A61P 1/04, 35/00 | | |
| Applicant HISAMITSU PHARMACEUTICAL CO., INC. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☐ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☐ Box No. VIII Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 22 October 2004 (22.10.2004) | 23 February 2005 (23.02.2005) |
| Name and mailing address of the IPEA/JP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/003804

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP03/03804

**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-14, 16, 17, 19-21, 23, 24, 26-36 | YES |
| | Claims | 15, 18, 22, 25 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-36 | NO |
| Industrial applicability (IA) | Claims | 1-36 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Documents cited in the ISR:
Document 1: WO, 98-05310, A1 (Hisamitsu Pharmaceutical Co., Inc.), 12 February, 1998 (12.02.98)
Document 2: WO, 94-10983, A1 (Hisamitsu Pharmaceutical Co., Inc.), 26 May, 1994 (26.05.94)
Document 3: WO, 99-59639, A1 (Hisamitsu Pharmaceutical Co., Inc.), 25 November, 1999 (25.11.99)

Explanation:

The subject matters of claims 15, 18, 22 and 25 do not appear to be novel in view of document 1 cited in the ISR.

Document 1 describes a capsule for an oral preparation, in which the surface of a capsule base is covered with a cationic copolymer and an anionic copolymer in succession, and also describes that the capsule can be disintegrated only when it reaches the large intestine, to efficiently release a pharmacologically active substance to be absorbed, and hence allows oral administration. The document also describes preparations useful for systemic diseases such as colic diseases like colorectal cancer and ulcerative colitis and osteoporosis as capsule preparations using the said capsule, and particularly discloses preparation examples containing 5-fluorouracil or budesonide as an active ingredient (Examples 6, 7 and 10).

The subject matters of claims 1-36 do not appear to involve an inventive step in view of documents 1-3 cited in the ISR.

Documents 1-3 respectively describe an oral medicinal preparation that (1) has a double covering structure in which a nucleus containing a pharmacologically active ingredient is covered with a cationic copolymer and an anionic copolymer in succession, and (2) can be disintegrated in the large intestine to release the pharmacologically active ingredient.

Furthermore, in medicinal preparations, it is a general practice of a person skilled in the art to adequately select and decide the particular disintegration capability and formulation of a preparation, the kinds of the base, additives and the drug used as an active ingredient, the contents of the respective ingredients, etc. in response to each purpose. A person skilled in the art could have easily selected them as required in the oral medicinal preparation described in any one of documents 1-3, to arrive at the subject matters of claims 1-36.